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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,125	01/09/2001	Tadamitsu Kishimoto	053466/0296	6506

7590 12/04/2001
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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/756,125

Applicant(s)

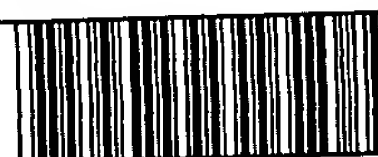
Kishimoto et al.

Examiner

G. R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Sep 20, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 9-17 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 9-17 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: _____

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644.

2. Claims 9-17 are being acted upon.

3. Claim 13 is objected to as having been improperly amended. The marked-up copy of the claim does not show the change from "The method" to "A method" as required under revised 37 CFR 1.121.

4. In view of Applicant's Terminal Disclaimer, filed 9/20/01, the previous double patenting rejection has been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9-17 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's Deposit Declaration, filed 9/20/01, indicates that the hybridoma designated FERM BP-2998 has been deposited under the provisions of the Budapest Treaty and that all restrictions on public availability will be irrevocably removed upon the granting of a patent based on the instant application. However, Applicant must further declare that said hybridoma will be maintained in a public depository for 30 years after the date of deposit, or 5 years after the last request for a sample, or for the enforceable life of the patent, whichever is longer. See MPEP 2408.

7. The following are New Ground for Rejection necessitated by Applicant's amendment, filed 9/20/01.

8. Claims 9 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does

not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: "an antibody including a complementary determinant region of an antibody produced by FERM BP-2998."

Applicant's amendment, filed 9/20/01, asserts that support for the amendment can be found on pages 10-11 of the specification. However, the cited pages do not provide support for the newly claimed sub-genus of antibodies comprising at least a single CDR of the antibody produced by FERM BP-2998. Note that a genus may not support a subgenus even though there is a disclosed species within the genus and a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads, *In re Smith* 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

9. Claims 9-17 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for: a method of inhibiting synovial cell growth comprising administering an antibody produced by FERM BP-2998, does not reasonably provide enablement for: a method of inhibiting synovial cell growth comprising administering an antibody including a complementary determinant region of the antibody produced by FERM BP-2998.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Antibodies are highly complex binding molecules comprising 6 complementary determining regions (CDRs) per binding site (see Figure 1, Bendig, 1995). The reference teaches that the engineering of a recombinant antibody comprising CDRs from one source and framework and constant regions from another does not necessarily create antibodies that bind the original antigen. In fact, even when all 6 CDRs are placed in the framework of the most closely related antibody as is possible, the resultant antibodies often "will show little or no binding to antigen" (page 86, column 2). Thus, the instant claims drawn to an antibody comprising just a single functional CDR, would be highly unpredictable. Given that the instant specification discloses no functional antibodies comprising just a single PM-1 CDR, said

unpredictability would be considered to require undue experimentation.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

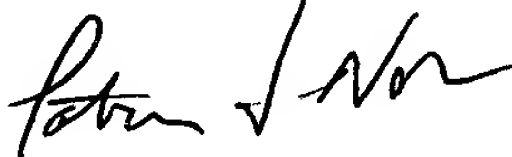
10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 8:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
November 26, 2001


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600